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## CSPC PHARMACEUTICAL GROUP LIMITED

## 石藥集團有限公司

(Incorporated in Hong Kong with limited liability)
(Stock Code: 1093)

## **VOLUNTARY ANNOUNCEMENT**

## NEW INDICATION FOR DUOENYI (IRINOTECAN HYDROCHLORIDE LIPOSOME INJECTION) OBTAINS MARKETING APPROVAL

The Board of Directors (the "Board") of CSPC Pharmaceutical Group Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that the new indication for the irinotecan hydrochloride liposome injection (brand name: Duoenyi) (the "Product"), developed by the Group has obtained marketing approval granted by the National Medical Products Administration of the People's Republic of China. The newly approved indication is for use in combination with oxaliplatin, 5-fluorouracil (5-FU) and leucovorin (LV) for the first-line treatment of patients with metastatic pancreatic cancer (the "Indication").

The approval of the Indication is primarily based on a pivotal clinical study enrolling patients with histologically or cytologically confirmed, unresectable locally advanced or metastatic pancreatic cancer who had not received prior systemic anti-tumor therapy. Results disclosed at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting showed that the Product significantly prolonged progression-free survival (PFS) in first-line treatment for advanced pancreatic cancer (hazard ratio (HR) of 0.55, representing a 45% reduction in the risk of disease progression or death), demonstrated a trend of benefit in objective response rate (ORR), duration of response (DOR), and overall survival (OS), and had a good safety profile, achieving reduced toxicity and enhanced efficacy compared with conventional formulations.

The Product was first approved for marketing in China on 15 September 2023. Its initial approved indication was for use in combination with 5-fluorouracil (5-FU) and leucovorin (LV) for the treatment of patients with metastatic pancreatic cancer who had progressed after receiving gemcitabine treatment, marking the first approval of an irinotecan hydrochloride liposome injection developed by a domestic enterprise in China. The indication approved this time is the Product's second approved indication in China and also the first approval of an irinotecan liposomal injection for first-line treatment of pancreatic cancer domestically. Currently, a pivotal registration Phase III clinical trial of the Product as adjuvant treatment after pancreatic cancer surgery is underway.

By order of the Board
CSPC Pharmaceutical Group Limited
CAI Dong Chen
Chairman

Hong Kong, 12 December 2025

As at the date of this announcement, the Board comprises Mr. CAI Dong Chen, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Mr. WANG Huaiyu, Dr. LI Chunlei, Dr. YAO Bing, Mr. CAI Xin, Mr. CHEN Weiping and Mr. QU Zhiyong as Executive Directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan, Mr. LAW Cheuk Kin Stephen and Ms. LI Quan as Independent Non-executive Directors.